



USDA Foreign Agricultural Service

GAIN Report

Global Agriculture Information Network

Template Version 2.09

Voluntary Report - public distribution

Date: 4/11/2007

GAIN Report Number: JA7025

Japan

Food and Agricultural Import Regulations and Standards

Comments Accepted on Changes to Packaging Standards

2007

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Report Highlights:

The Japanese MHLW is accepting comments on proposed changes to 1) Specifications and Standards for Containers and Packages for Cow's Milk and Milk Products made of Polyethylene Terephthalate Resin and 2) Revision of Test Methods and Specifications for Apparatus and Containers/Packages for Retort Pouch Food 3) Specifications and Standards for Apparatus and Containers/Packages made of Polylactic Acid Resins. Comments are due by April 24, 2007.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Tokyo [JA1]
[JA]

On April 10 the Ministry of Health Labour and Welfare announced the intention to make the following changes: 1) Establishment of Specifications and Standards for Containers and Packages for Cow's Milk and Milk Products made of Polyethylene Telephthalate Resin 2) Revision of Test Methods and Specifications for Apparatus and Containers/Packages for Retort Pouch Foods and 3) Establishment of Specifications and Standards for Apparatus and Containers/Packages made of Polylactic Acid Resins.

Comments on these proposed changes are being accepted until April 24, 2007. If you have comments it is best to send directly to MHLW as soon as possible, however MHLW will also notify these proposed changes to the WTO/SPS committee, which will provide another chance for public comments to be submitted on this subject. Then after the closing of the comment period in the WTO, a final report will be made based on the conclusions of a session of the Pharmaceutical Affairs and Food Sanitation Council slated to be held at a later date, and this will constitute the final decision.

If you have comments, please send them directly to the Japanese Government at:

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Pharmaceutical and Food Safety Bureau,
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Item 1)

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The comments can be in either English or Japanese. Please also consider copying the U.S. Embassy, Tokyo at agtokyo@usda.gov on your comments in order for them to be considered as part of the official U.S. Government comments to the WTO.

Details of proposed changes:

1) Establishment of Specifications and Standards for Containers and Packages for Cow's Milk and Milk Products made of Polyethylene Telephthalate Resin

Purpose and background

This activity is to expand the scope of synthetic resins which can be used as materials of containers and packages for normal milk and other certain milk products for sale.

The Food Sanitation Law defines "container and package" as an article in which a

food or additive is contained or packed and with which the food or additive is offered when it is delivered. Containers and packages for milk or milk products are regulated both by the Ministerial Ordinance concerning Compositional Standards, Etc. for Milk and Milk Products (originally specified in Ministerial Ordinance No. 52, 1951) and by the Specifications and Standard for Food and Food Additives, Etc (originally specified in Ministry of Health and Welfare Notification No. 370 in 1959).

The Ministerial Ordinance specifies synthetic resins that can be used as materials of containers and packages for milk and milk products for sale. Any person is not permitted to use materials other than specified ones. This time the Ministry of Health, Labour and Welfare has decided to permit the use of polyethylene terephthalate resin (PET) as the materials for containers for normal milk, certified milk, pasteurized goat milk, modified milk, partly skimmed milk, skimmed milk, processed milk, and cream for sale, in response to a request from the related industry. The MHLW will establish necessary specifications for PET used for this purpose.

The MHLW has already received a report from the Food Safety Commission that the use of PET is unlikely to pose any problem with safety as long as PET-bottled milk and milk products are controlled under appropriate conditions. This report is underlain by the fact that the safety of PET, which is already used for containers for non-milk beverages and certain milk products such as formulated milk powder, is ensured.

Outline of additional specifications

The Ministry of Health, Labour and Welfare will permit the use of synthetic resins which can be used as materials of containers and packages for normal milk and other certain milk products for sale.

1. Containers and packages for normal milk, certified milk, pasteurized goat milk, modified milk, partly skimmed milk, skimmed milk, processed milk, and cream for sale. Synthetic resins whose use is permitted as materials of milk containers

--PET resin and PET-processed paper will be added.

--PET resin will be permitted for use as a material of parts coming into direct contact the food.

2. PET containers and packages shall meet the following tests.

Material tests

- Cadmium and lead: Not more than 100 ppm

Elution test

- Heavy metals: Not more than 1 ppm
- Residue on evaporation: Not more than 15 ppm
- Potassium permanganate consumption: Not more than 5 ppm
- Antimony: Not more than 0.025 ppm
- Germanium: Not more than 0.05 ppm

Strength tests

- Sealing strength: Not less than 13.3 kPa
- Pinholes: No spot shall be formed on the filter paper.

Either of the following tests

- Bursting strength

—Containers with a capacity of not more than 300 ml: Not less than 196.1 kPa (not less than 392.3 kPa in case of foods which can be kept at room temperature)

—Containers with a capacity of more than 300 ml: Not less than 490.3 kPa (not less than 784.5 kPa in case of foods which can be kept at room

temperature)

- Piercing strength: Not less than 9.8N

Specifications for Synthetic Resin Containers and Packages

Category	Test item	Method/condition	Material			
			PE/LDPE	NY	PP	PET
Material test	Diffusion coefficient		≤2.0%	—	—	—
	Extraction residue (oil, fat, etc.)		≤71.3%	—	—	—
	Acidity		≤2.0 g/L	—	—	—
	Heavy metals		≤20 ppm	—	—	—
	Chlorine	50°C, 48 hr	—	—	—	≤100 ppm
	Loss	At 100°C, 24 hr, 100% relative humidity	—	—	—	≤100 ppm
Microbiological test	Heavy metals	5% Acetic acid	≤1 ppm	≤5 ppm	≤1 ppm	≤1 ppm
	Polyethylene (non-polyethylene)	Water	≤1 ppm	≤5 ppm	≤5 ppm	≤5 ppm
	Residue on compression	at 100°C	≤10 ppm	—	—	≤10 ppm
		20% Ethanol	—	—	—	—
		Water	—	—	—	—
	Acidity	4% Acetic acid	≤10 ppm	≤5 ppm	≤10 ppm	≤10 ppm
	Chlorine	5% Acetic acid	—	—	—	≤100 ppm
Strength test	Tearing strength	—	≥1530 N			
	Impact	—	No mark shall be formed on the impact point			
	Bursting strength ¹⁾	At 90°C at 0.1 MPa	≥186 MPa			
		At 90°C at 0.1 MPa in case of foods which can be heated at room temperature	≥202 MPa			
	Piercing strength ²⁾	At 90°C in case of foods which can be heated at room temperature	≥204 MPa			
Others			—	—	—	≥9.8N

①: PE, LDPE (Linear Low Density Polyethylene), etc.; NY: Polyamide; PP: Polypropylene; PET: Polyethylene terephthalate.

1: 0.1 MPa is applied to each.

2: For PET that uses either of the bursting strength test and piercing strength test.

2) Revision of Test Methods and Specifications for Apparatus and Containers/Packages for Retort Pouch Foods

Purpose and Background

This activity is to develop the specifications for containers and packages for retort pouch foods.*

Based on Article 18 of the Japanese Food Sanitation Law, apparatus and containers/packages for foods shall meet the specifications and standards (specified in Part 3 "Apparatus and Containers/Packages" of the Specifications and Standards for Food and Food Additives: originally published in Ministry of Health and Welfare No. 370, 1959). Specifically, they shall pass the heat-sealing strength test as well as other required tests.

The heat-sealing strength test was established in 1977, targeted at pouch-type containers. In the recent years, various types of containers have been developed besides the pouch-type, such as the cup-type, tray-type, and box-type, along with advances in technology. The test, however, is not appropriate to examine the strength of container styles such as the box-type. Given such a situation, the Ministry of Health, Labour and Welfare has decided to establish an additional strength test (as an alternative).

Outline of Revision

The internal pressure strength test will be established as an additional [alternative] strength test, and a requirement will be added to specifications for containers and packages for retort pouch foods. For details, see the attachment 5-1.

* Retort pouch foods refer to products which are packed in containers or packages and which are pasteurized under pressure, except for canned foods and glass-bottled foods.

* * The package must comply with one of these two tests, whichever is more appropriate

Attachment 5-1

Part 3 Apparatus and Containers/Packages

B. General Tests

2. Strength Tests

Internal pressure strength

Stick an air needle through the sample container which is filled with intended food or water and tightly sealed, and fasten the needle so that the inner air cannot leak. Connect a pressure gauge and a compressor to the needle. Send air through the needle into the container at a rate of 1 ± 0.2 L/min. Read the maximum pressure applied when it is burst. (Refer to the test apparatus below.)

E. Specifications for Apparatus and Containers/Packages According to Use

1. Containers and Packages for Retort Pouch Foods

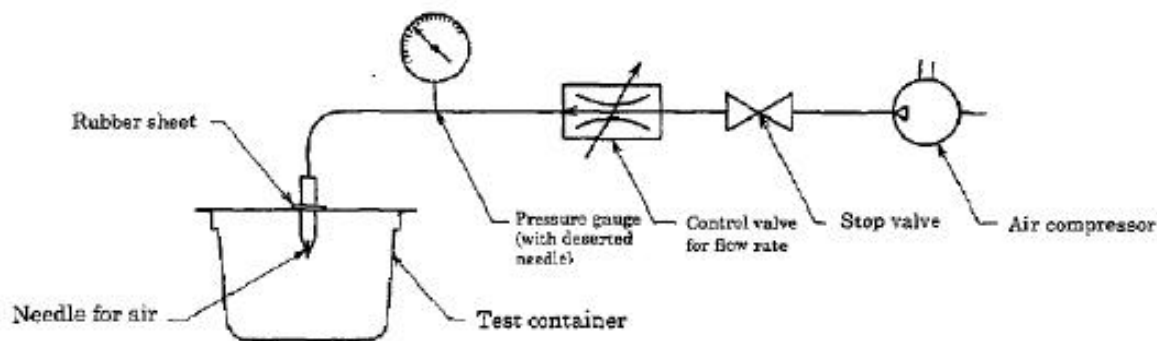
(4) The measured value shall be 23N or more when the container is subjected to heat-sealing strength test. For the box-type containers and packages (including cup and tray-types), the internal pressure strength test may replace the heat-sealing strength test; the maximum pressure applied when it is burst shall be 20 kPa or more.*

Note: The underlined part is the newly added requirement.

Apparatus

The test apparatus must consist of a metallic air needle to supply air into the test container, a hose to introduce air, a pressure gauge, and air source such as an air compressor. It must

be of a structure that is able to read the pressure inside the test container when the container is burst due to the air introduced into it.



Item 3) Establishment of Specifications and Standards for Apparatus and Containers/Packages made of Polylactic Acid Resins

Purpose

This activity is to develop specifications and standards for food apparatus and containers/packages made of synthetic resins and ensure the safety of these products.

Synthetic resins whose main component is polylactic acid (PLA) are already in commercial use in Japan as eating utensils. In Europe and the United States, these resins are used for a wider variety of purposes including as throw-away eating utensil and as food containers. They are expected to be widely used in Japan as well. Given such situation, the Ministry of Health, Labour and Welfare has decided to newly establish specifications and standards for PLA resin apparatus, containers, and packages for foods. The Food Sanitation Law regulates apparatus, containers, and packages for foods. They shall meet specifications and standards under the law.

Outline of establishment

The law specifies two types of specifications—general specifications and individual specifications—in Item 2 “Apparatus and Containers/Packages Made of Synthetic Resins” in Section D “Specifications for Apparatus and Containers/Packages According to Material” in Part 3 “Apparatus and Containers/Packages” in the Specifications and Standards for Food and Food Additives (specified in Ministry of Health and Welfare Notification No. 370 in 1959).

Individual specifications will be newly established for the new category “PLA resin apparatus and containers/packages.” Also, some requirements will be established in Section F “Standards for Manufacturing.” In step with the establishment of the specifications, Sections B and C of Part 3 will be revised. In Section B the test method of total lactic acid will be newly established as a monomer test and in Section C some reagents and standards solutions will be added. After the implementation of the revision, the PLA resins will be

subjected to the individual specifications and the existing general specifications for synthetic resins based on the Food Sanitation Law. See the attachment 5-2 for details.

Attachment 5-2

Apparatus and Containers/Packages

B. General Tests

8. Monomer tests

Total lactic acid

(1) Identification test

Measure 1 ml each of the sample solution and lactic standard solution, add 100 μ l of 0.2 mol/l sodium hydroxide, and stopper. Allow them to stand for 15 minutes with occasional shaking while maintaining at 60°C. After cool, add 100 μ l of 0.2 mol/l phosphoric acid to each. Using a 100 μ l portion for each solution, perform liquid chromatography according to the conditions given below, and compare the peak detection time in the chromatogram of the test solution to the peak detection time in the chromatogram of the lactic acid standard solution.

Operating conditions

Column: A stainless steel with an internal diameter of 4.6 mm and a length of 250 mm in Column packing material: Octadecylsilanized silica gel

Column temperature: 40°C

Detector: A ultraviolet spectrophotometric detector (detection wavelength: 210 nm)

Mobil phase: A mixture of phosphoric acid, acetonitrile, and water (0.1:1:99)

Adjust the flow rate so that lactic acid flows out in about 5 minutes.

(2) Quantitative test

Perform the following test when in the qualification test (1) the peak detection time of the sample solution matches the peak detection time of the standard solution. Using the results obtained under the conditions given in the qualification test (1), measure the peak area of lactic acid in the sample solution. The peak area should not be greater than the peak area of the lactic acid standard solution.

C. Reagents and Solutions

Reagents

L-Lithium lactate $\text{CH}_3\text{CH}(\text{OH})\text{COOLi}$ Contains at least 97% of lithium lactate ($\text{CH}_3\text{CH}(\text{OH})\text{COOLi}$).

Phosphoric acid H_3PO_4 [K9005, Special grade]

Solutions

0.2 mol/l sodium hydroxide Dissolve 8.0 g of sodium hydroxide in water, and add water to make 1,000 ml.

0.2 mol/l phosphoric acid Add water to 14 ml of phosphoric acid to make 1,000 ml.

Standard solution

Lactic acid standard solution Add water to 1.07 g of L-lithium lactate, exactly weighed, to make 1,000 ml. Measure 3 ml of this solution, and add water to make

1,00 ml. One ml of this solution contains 30 µg of lactic acid.

D. Material Specifications

<Synthetic resins>

Individual specifications

Item 13. PLA resins

Apparatus and containers/packages made of PLA resins shall pass the following tests.

a. Migration tests

i. Total lactic acid (Not more than 30 µg/ml)

The specification for total lactic acid shall be met when the test is performed as directed in the monomer tests, using water as a stimulant.

The total lactic acid in the sample solution is not more than 30 µg/ml, if the product meets the requirement.

ii. Residue on evaporation (Not more than 30 µg/ml)

The residue shall be not more than 30 µg/ml, when test is performed as directed in the residue on evaporation test.

F. Standards for Manufacturing

PLA containing more than 6% (weigh) D-lactic acid shall not be used as an ingredient of apparatus or containers/packages which are expected to be used at a temperature over 40°C. However, this requirement does not apply to products which are used for up to 2 hours at a temperature of more than 40°C and not more than 66°C or which are used for up to 30 minutes at a temperature of more than 66°C and not more than 100°C.